REMARKS

1. Group Restriction Requirement

a. Group I and II claims should be considered together

In response to the present Restriction Requirement, Applicants elect with traverse Group I, claims 26 and 29-43 (in part), drawn to a method for determining the susceptibility to a disease associated with β-amyloid formation/aggregation, for further examination.

Applicants respectfully disagree with the examiners characterization of the proposed invention as "distinct" in paragraph 3 of the Office Action. The Office Action states:

> The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not natural variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

The Group I and Group II portions of claims 26 and 29-43 overlap in scope as both are intimately related to the disclosed function as "methods for the diagnosis of diseases associated with β-amyloid formation and/or aggregation" (Abstract). Such diseases include but are not limited to: Dementia with Lewy bodies (DLB) with amyloid, Down's Syndrome, and differing forms of Alzheimer's disease. (Published specification, p. 5, ¶ 64).

In paragraph 3, the Examiner further suggests an alternative method for detecting β-amyloid formation in the Group I claims using short tandem repeat primers. The Examiner's suggestion is presumably based on the specification disclosure that genetic mutations cause abnormal APP metabolism in patients with familial autosomal dominant Alzheimer's disease (FAD AD). (Published Specification, p. 1, ¶ 8) The presence of the mutation, however, does not mean that APP proteolysis will necessarily occur. The specification further discloses that FAD AD patients represent about 1 % of all AD patients. Id. β-amyloid formation is not the result of genetic mutation in the other 99 % of AD patients, or the other β-amyloid related diseases described above. Id.

To be clear, nearly all cases the truncated Aβ forms are not a result of gene mutations; rather, they are result of the abnormal proteolytic cleavage of APP peptide and indicate aberrant APP metabolism. Gene mutations cannot predict the formation of N-truncated Aβ forms; it is the presence of such Aβ forms that are used to predict the onset of

the disease. Accordingly, a method of detecting the presence of such Aβ forms is immunological and requires aid of fragment specific antibodies. The specification and Group II claims, thus, describe a complementary variation of diagnosing AD patients based on Aβ clearance. Id. Accordingly, the Applications respectfully request that the Examiner withdraw the restriction requirement for Groups I and II.

b. Some Group III claims should be considered with Group I and II claims

The Applicants have withdrawn claims 52 and 54 designated by the Examiner as Group III claims. Further, the Applicants have amended claim 44 and the related dependent claims as "for use in the method of claim 26". Group III kit claims now relate to the method invention of claims 26, 29-38, and 40-43. As described above in Section I.a, the Examiner's suggestion for using short tandem repeat primers is not an appropriate solution to the problem addressed by this application. Likewise, Examiner's suggestion that the presence of presenilin or γ-secretase may serve as markers is not beneficial. Those enzymes are naturally occurring and are not predictive of diseases caused by atypical β-amyloid formation and/or aggregation. The Group I and II method claims require fragment specific immunological detection, and the Group III claims that provide a means for accomplishing such detection. Accordingly, the Applicant Respectfully requests that the Examiner also withdraw the restriction requirement for the currently pending Group III claims.

In the alternative, Applicants submit that the Group III product claims should be rejoined with the process claims of Groups I and II and fully examined for patentability upon the allowance of the process claims in accordance with the provisions of MPEP § 821.04.

2. Group Restriction Requirement

In response to the present Group Restriction Requirement at paragraph 7 of the Office Action, Applicants elect from **Group A**, N-terminal truncated/post-translationally modified β-amyloid variant. Applicants elect from **Group B**, A peptide.

3. Species Election Requirement

In response to the present Species Election Requirement at paragraph 12 of the Office Action, Applicants elect from:

(i): C) start position 4, which reads on species claims 31, 32, 33; Claim 26 is generic thereto.

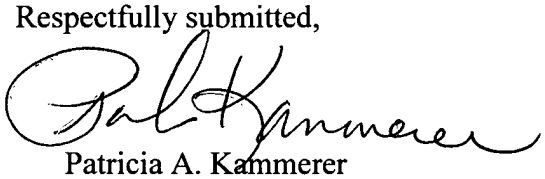
(ii): C) methylation at position 4, which reads on species claim 36; Claims 26 and 35 are generic thereto.

(iii): the molecule Aβ (4-42), which reads on species claim 34; Claim 26 is generic thereto.

In regard to subsection (iii) of the Species Election Requirement, the Applicants believe that the Examiner may have overlooked claim 34, which claims more that just Aβ (5-42) or Aβ (8-42). If there was an oversight, the applicant elects Aβ (4-42) for examination of the method claims. However, in the event that Examiner requires an election of only either Aβ (5-42) or Aβ (8-42) as presented in claims 43 and 48, the Applicants elect the molecule Aβ (5-42), which reads on species claims 43 and 48.

This paper is filed after the one-month time for reply but within the statutory period. The Commissioner is authorized to deduct the fee for the one month extension for this response from Howrey LLP Deposit Account No. 01-2508/**11362.0039.NPUS01**. It is believed that no other fees are due for this application under 37 C.F.R. §§ 1.16-1.22. If any fee is due for this application, however, the Commissioner is authorized to deduct the fee from the Deposit Account listed above.

Respectfully submitted,



Patricia A. Kammerer
Reg. No. 29,775
Attorney for Assignee
INNOGENETICS N.V.

Customer No. 23369
HOWREY LLP
1111 Louisiana, 25th Floor
Houston, Texas 77002
(713) 787-1512 (direct)

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